

Application No. 10/517,788

REMARKS**I. The Status of the Claims**

Claims 5-7 and 9-12 are canceled.

II. The Indication of Allowable Subject Matter

Applicants greatly appreciate the indication that claims 1-2 are free of the prior art.

III. The Rejections Under 35 U.S.C. § 112, First Paragraph**The Rejection of Claims 4 and 5 for Lack of Written Description for "Microorganism"**

The Office Action rejects claims 4 and 5 under 35 U.S.C. § 112, first paragraph. In particular, the Office Action asserts that the claims lack written description for the microorganism. In response, Applicants submit that the specification provides sufficient support for "microorganism". See, for example, the specification, which discloses:

In the course of a screening program designed to identify new antitumour compounds (cytotoxics), a new bafilomycin-like metabolite was isolated. The same metabolite was isolated from liquid fermentation cultures of two different actinomycete of the genus *Micromonospora*. *Micromonospora* spp. JS1035 was isolated from river sediments from Sombo, Cameroon while *Micromonospora* spp. JS1044 was isolated from river sediments from Mundemba, Cameroon. As soon as it was detected that both strains produced the same active compound it was decided to further characterize the compound present in liquid fermentation cultures from *Micromonospora* spp. JS1035. A culture of each micro-organism utilised for the production of these new macrolide have been deposited in the Laboratory for Microbiology in the Belgian Coordinated Collections of Microorganism at the University of Gent under accession number LMG P-21525 for *Micromonospora* spp. JS1035 and under accession number LMG P-21526 for *Micromonospora* spp. JS1044. These deposits have been made under the provisions of the Budapest Treaty and all restrictions on the availability thereof to the public will be irrevocably maintained upon granting of a patent on this application.

Application No. 10/517,788

Reconsideration and withdrawal of the rejection of claims 4 and 5 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

The Rejection of Claims 3-5

The Office Action rejects claims 3-5 under 35 U.S.C. § 112, first paragraph. In particular, the Office Action asserts that the claims "lack operable steps and parameter." In response, Applicants submit that the amendment to claims 3- 5 obviate any basis for this aspect of the rejection. Reconsideration and withdrawal of the rejection of claims 3-5 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

The Rejection of Claims 4 and 5 for Lack of Enablement for "Microorganism"

The Office Action rejects claims 4 and 5 under 35 U.S.C. § 112, first paragraph. In particular, the Office Action asserts that the claims lack enablement for the microorganism. In response, Applicants submit that the cancellation of claim 5 and amendment to claim 4 obviates any basis for this aspect of the rejection. Furthermore, as discussed above, the present specification provides sufficient guidance to one skilled in the art as to the meaning of the presently claimed microorganism. Reconsideration and withdrawal of the rejection of claims 4 and 5 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

Application No. 10/517,788

The Rejection of Claim 8 for Lack of Written Description and Enablement for "Method for Treatment of Cancer"

The Office Action rejects claim 8 under 35 U.S.C. § 112, first paragraph, for lack of written description and enablement. In particular, the Office Action asserts:

Applicant has shown the nexus between formula (I) and the treatment of specific cancers such as ovary, prostate, pancreas, colon, and lung. However, applicant has not shown the nexus for using compound of formula (I) and treating any other types of cancers.

In response, Applicants submit that although the specification provides examples of a few types of cancers that may be treated with the claimed compound, the claims should not be limited.

The Office Action has not provided any evidence to suggest that the claimed compound would not be effective in other types of cancer. The present specification discloses:

The compound of formula (I) was extensively characterized for its ability to inhibit tumour cell growth. The dose-dependent inhibition of the compound of formula (I) in four selected tumour cell proliferation assays was typical for classical cytotoxics, with very steep and narrow dose-response curves. Initial observation on inhibition of tumour cell proliferation was extended to a wide variety of human tumour cell lines, from ovary, prostate, pancreas, colon and lung origins, with observed IC₅₀ values in the nM range of concentrations.

Reconsideration and withdrawal of the rejection of claim 8 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

IV. The Double Patenting Rejection

The Office Action objects to claim 6 as being a substantial duplicate of claim 1. In response, Applicants submit that the cancellation of claim 6 obviates any basis for the objection.

Reconsideration and withdrawal of the objection to claim 6 are respectfully requested.

Application No. 10/517,788

V. Conclusion

Early consideration and prompt allowance of the pending claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number listed below.

Respectfully submitted,

/Laura A. Donnelly/

By: _____
Laura A. Donnelly
Registration No. 38,435
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
Telephone: 732-524-1729
Facsimile: 732-524-2808
Dated: June 20, 2006